

K933469

**SUMMARY OF SAFETY AND EFFECTIVENESS OF  
UNIVAC NONREUSABLE LOCKING SYRINGE**

**(1) Submitter's Information:**

UNIVAC, Inc.  
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Garden City, New York 11530  
(516) 294-1000 (tel)  
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**(2) Device Name:**

Proprietary Name: Model 884 Umbrella Nonreusable Syringe

Common or Usual Name: Piston, Hypodermic Needle

Classification Names: Piston Syringe  
21 C.F.R. 880.5860 Class II

Hypodermic Single Lumen Needle  
21 C.F.R. 880.5570 Class II

**(3) Predicate Devices:**

UNIVAC Nonreusable Locking Syringe (K943679)

FLP Enterprises LOKSHOT Syringe (K891467)

**(4) Description of Device:**

The UNIVAC Model 884 Umbrella Nonreusable Syringe is a sterile piston syringe with 1 cc or 0.5 cc capacities fabricated of polypropylene. It has a locking device made of the same polypropylene material. The "umbrella" description describes the locking mechanism which emulates the shape and functioning of an umbrella.

Functioning in the traditional manner, this syringe is capable of aspirating and mixing various serums in its barrel by health practitioners and individuals for subsequent injection. It can be locked or prevented from further use by depressing the plunger toward the forward end of the barrel (and past noticeable resistance) in order to activate the locking device. Further use of the syringe is thus prevented.

**(5) Statement of Intended Use**

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This syringe is intended for diabetics who inject insulin and healthcare professionals who inject insulin, tuberculin or immunization serum and other injectible medications.

(6) Statement of Technological Characteristics

The UNIVAC Nonreusable Syringe has no significant change in design, material, chemical composition, energy source or other characteristics compared to the predicate devices listed. The locking device, fabricated of polypropylene, the same material as the rest of the syringe, is the only difference with one of the predicates, the UNIVAC Model 888 Nonreusable Locking Syringe (K943679), (its locking device is made from stainless steel 304). There are no differences with the FLP Enterprises LOKSHOT Syringe, # K891467